REMARKS

Applicants intend this response to be a complete response to the Examiner's **17 December 2003 Final Office Action**. Applicants have numbered the paragraphs in their response to correspond to the paragraph numbering in the Office Action for the convenience of the Examiner. Please note that related paragraphs are combined in paragraph number ranges, *e.g.*, 2-3.

General Remarks

The present invention is not obvious over any of the cited reference taken alone or any combination. In fact, the inventor can document prior invention of his device over Takashina et al. However, because Takashina et al clearly teaches away from the present invention (generating pressure pulses without mechanical vibrations - a requirement of this invention), Applicant utilizes Takashina et al to demonstrate how non-obvious the present invention is based on the prior art cited in this Office Action.

Eggert et al.

Applicants are also respectfully perplexed by the Examiner's continued miss reading of Eggert et al. Eggert et al. simply does not include a touch discernible device for simulating a pulse. Eggert et al. does disclose tactile switches, but they are ON/OFF switches used to ensure proper placement of an oximeter (oxygen sensor) on the finger of the manikin and a blood pressure device on the arm of the manikin . These switches are not capable of generating a pulse, no more that an light switch is capable of generating light. The tactile switches of Eggert et al. simply complete a circuit as does a light switch; the only difference being that one requires a toggle motion to turn on and off, while the other requires a pressure to turn on and off. But they are not devices for simulating a pulse.

Claim Rejections - 35 USC § 103

3. **Claims 1 and 2** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Eggert et al (US 6, 193,519) in view of Lampotang et al (US 5,769,641). Applicant traverses this rejection and requests reconsideration in light of the claim amendments, if any, and the remarks set forth below.

The Examiner contends as follows:

> Regarding claim 1, Eggert et al discloses a simulation apparatus comprising a plurality of electronic signals corresponding to a heart beat (Col 4, lines 46-62), a tactile pulse signal to detect a pulse signal discernable by touch (Col 6, lines 26-40), and an audio simulator for generating a heart beat signal (Col 4, lines 46-62). Eggert et al does not specifically disclose the generation ora pulse signal or a correlated heart sound. However, Lampotang et al teaches a simulation system which generates a pulse signal and a synchronized heart sound. Therefore; it would have been obvious to one of ordinary skill in the art at the time of invention to provide a system comprising a plurality of electronic signals corresponding to a heart beat, a tactile pulse signal to simulate a pulse signal discernable by touch, and an audio simulator for generating a correlated heart beat signal. Combining the system disclosed by Eggert et al with the teaching of Lampotang et al produces a system that closely corresponds to a real patient.

Applicant acknowledges that Eggert et al. generates sounds, particularly heart beat sounds. However, Applicant disagrees the Eggert et al. includes pulse simulators that generate a tactile output designed to be detected by touch. The tactile switches of Eggert et al are designed to ensure proper attachment of the cuffs **18d** and **18e** to the manikin.

> FIGS. 5a-5d illustrate details of the **BP** cuff **18*d*** and the **pulse oximeter** finger cuff **18*e***. The cuffs **18*d*, 18*e*** are configured together wherein a cable **86** is provided that connects to the BP/OSAT/HEARTRATE port **48** and bifurcates into the respective cuffs. Electrical leads **86a** and **86b** connected to the respective cuffs **18*d*** and **18*e*** are depicted at one end of the cable **86** in FIG. 5b for connection to the EKG port **48** (FIG. 3). As shown in FIGS. 5c-5d with respect to the finger cuff **18*e***, a tactile switch **88** connected to a line **90** of the cable **86** is mounted in the finger cuff and is activated to complete a circuit when the cuff is secured properly with velcro (male) **91*a*** and velcro (female) **91*b*** to the finger of the manikin **28**. Similar switch circuitry, though not shown, is contained in the BP cuff **18*d***.

Eggert et al. at Col. 6, ll. 26-40 (emphasis added). Applicant is absolutely perplexed by the Examiner continued assertions that Eggert et al. teach a tactile device which allows a person to feel a pulse. The cuffs of Eggert et al. are associated with an oximeter device and a blood pressure device. An oximeter device is defined as follows: "A photoelectric device that measures the amount of oxygen inblood and other fluids." http://www.books.md/O/dic/oximeter.php. The switches of Eggert et al. are designed solely to complete a circuit, not to generate touch discernable simulated pulse. While a blood pressure device is designed to measure blood pressure. **The only purpose the tactile switches of Eggert et al. serve is to ensure that the student can properly attach an oximeter to the finger of a patient and to properly attach a blood pressure device to a patient.** The Examiner's position on this matter is simply unsupported by the disclosure of Eggert et al. Eggert et al. simply does not disclose, teach or suggest an apparatus including a tactile response system for generating a touch discernible pulse simulation and an audio response system for reproducing heart sounds in a correlated manner.

Moreover, Eggert et al. uses virtual instruments. The entire purpose of the present invention is to require a student to use his/her senses and an actual stethoscope to learn the proper use of the stethoscope in the care and early diagnosis of metal diseases and dysfunctions. The problem solved by this invention is the fact that medical students often graduate without basic skills in utilizing their fingers and a stethoscope as a first line diagnostic for detecting heart and/or circulatory abnormalities. Using virtual instruments regardless of their sophistication does not over come this problem.

When using the present invention, the student is confronted with recordings of real heart sounds and correlated touch discernable pulse simulations that require the students to hone their skills in distinguishing normal heart and circulatory rhythms from abnormal heart and circulatory rhythms.

In its simplest form, the present invention comprising a playback device, a tactile output device and an audio output device. A student places her/his finger on the tactile

output device and the listening end of a stethoscope on the audio output device, and the playback device sends correlated pulse signals and heart sound signals to the output devices.

Nothing in Eggert et al. discloses, teaches or suggests combining two different sensory output devices (speaker and a tactile output device) to educate a student on the proper use of a hands on technique for front line diagnostics using correlated output signals. **Again, Eggert et al. only uses tactile switches to complete a circuit ensuring that the student has properly positioned an oximeter - oxygen sensor and a blood pressure device on a simulated patient.**

Lampotang et al. does nothing to eliminate the basic deficiencies of Eggert et al. While Lampotang et al. does relate to a simulator for simulating human responses during medical procedures, the manikin is capable of generating lung and heart sounds, but only the lung sounds are synchronized with anything: "normal and abnormal breath sounds are synchronized with the bellows movement." Lampotang et al. at Col. 12, ll. 38-40.

As far as Applicant's attorney can determine, the Lampotang et al. manikin does not include any tactile output devices. Applicant's attorney searched the patent extensively for every conceivable verbal description of such as a device and found none.

Moreover, Lampotang et al. does not disclose, teach or suggest ensuring that the heart sounds and pulses going to the EKG are correlated. Clearly, the pulse network is synchronize so that pulse propagation profiles can be simulated in the device. However, this pulse simulation system does not produce a signal detectable by touch – no tactile devices.

Therefore, a combined Eggert et al. and Lampotang et al. device would have no mechanism of outputting a touch discernible pulse simulation correlated to heart sounds, because neither reference includes a device that a student can touch and discern a pulse. Thus, the combined device fails to include or suggest a touch output device or correlating touch and sound, the two key ingredients in a device of this invention designed to train medical students in the proper use of a stethoscope and touch as a front line diagnostic.

Because neither Eggert et al., Lampotang et al. nor their combination disclose, teach or suggest a device including a tactile sensory output device (touch discernible), especially one correlated to heart sounds, the present invention is therefore clearly not obvious for Eggert et al in view of Lampotang et al. Applicant, therefore, respectfully requests withdrawal of this section 103(a) rejection.

The Examiner contends as follows:

> Regarding claim 2, Eggert et al discloses a simulation apparatus comprising a plurality of electronic signals corresponding to a heartbeat (Col 4, lines 26-45) distributed in an appropriate fashion, left side or right side, required by the training regimen (Col 6, lines 40-52), and an audio simulator for generating a heart beat signal (Col 4, lines 26-45) that may be heard through a stethoscope. Eggert et al does not specifically disclose the generation of a pulse signal or a correlated heart sound. However, Lampotang et al teaches a simulation system which generates a pulse signal and a synchronized heart sound. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a system comprising a plurality of electronic signals corresponding to a heart beat, a tactile pulse signal to simulate a pulse signal discernable by touch, and an audio simulator for generating a correlated heartbeat signal in an appropriate position, whether that is the left or right side. Combining the system disclosed by Eggert et al with the teaching of Lampotang et al produces a system that provides more flexibility for training staff.

Applicant incorporates the previous arguments herein, and further notes that claim 2 is not obvious in view of Eggert et al. and Lampotang et al. because claim 2 differs from claim 1 only in the addition of a second tactile output device.

Again, the Examiner is just late mistaken in his reading of Eggert et al. Eggert et al. does not disclose, teach or suggest a touch discernible output device for simulating a pulse, especially one correlated to a heart beat so that a student and hear and feel normal verses abnormal cardio-vascular rhythms. Thus, the present claims are not disclosed, taught or suggested in Eggert et al, Lampotang et al or their combination.

Because neither Eggert et al, Lampotang et al nor their combination disclose, teach or suggest a device including a tactile sensory output device, especially one correlated to

heart sounds, the present invention is not obvious for Eggert et al in view of Lampotang et al. Applicant, therefore, respectfully requests withdrawal of this section 103(a) rejection.

4. **Claims 8-27** stands rejected under 35 U.S.C. 103(a) as being unpatentable over Eggert et al in view of Lampotang et al in further view of Takashina et al (US 6,461,165). Applicant traverses this rejection and requests reconsideration in light of the claim amendments, if any, and the remarks set forth above and below.

The Examiner contends as follows:

> Regarding claim 9, Eggert etal discloses that the audio simulator housed within a housing (Col 4, lines 37-44 and Fig. 2). Eggert et al does not specifically disclose a tactile simulator housed within a housing. However , Takashina et al. teaches that a tactile simulator may be housed within a housing that simulates a manikin (Col 2, lines 22-35). Therefore, it would have been obvious to one of ordinary skill in 1he art at the time of invention to provide a simulator with audio and tactile simulators housed within a housing. Combining the system disclosed by Eggert et al with the teaching of Takashina et al provides a system that is more self- contained and easily used.

Applicant incorporates the previous arguments herein, and further notes that Takashina et al does not remedy the deficiencies of Eggert et al. or Eggert et al. in view of Lampotang et al. **Again, Eggert et al. does not include a pulse simulation device.** Applicant hereby formally antedates Takashina et al. as the date of invention is prior to the July 6, 1999 United States filing date of Takashina et al. as evidenced by the attached invention disclosure statement for the University of Texas Medical Branch. Takashina et al. uses air to generate a simulated pulse "without generating any mechanical vibration." Takashina et al. at Col 2, ll. 24-25. Adding Takashina et al. to Eggert et al. or Eggert et al. combined with Lampotang et al. gives rise to an air activated pulse/heart sound simulator. In fact, Takashina et al., by requiring pulse generation without mechanical vibration, teaches squarely away from the present invention that is directed to a device that directly generates a mechanical vibration in the form of a tactile output device producing mechanical vibrations in a material such as a piezoelectric transducer to simulate a pulse.

Moreover, the present invention is distinguished from these references in that the pulses are mechanically generated by a touch discernible tactile subsystem and correlated with heart sounds generated by an audio subsystem discernible with a stethoscope.

Because the combination of these three references does not disclose, teach or suggest a combination of mechanical pulse generators coupled with audio output devices for correlated heart sounds and in fact the addition of Takashina et al teaches squarely away from using mechanical or electromechanical devices to generate the pulse, the combination does not render claim 9 obvious. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claims 11 and 17, Eggert et al discloses that the audio simulator housing is contained by a simulator that simulates an upper part ora human body including simulated chest and arm portions (Col 2, lines 27-54 and Figure 2). Eggert et at does not specifically disclose a tactile simulator housing that is contained by a simulator that simulates an upper part of a human body including simulated chest and arm portions. However, Takashina et al teaches that a tactile simulator may be housed within a housing that simulates a manikin including simulated chest and arm portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator with audio and tactile simulators housed within a simulator that simulates an upper part of the human body including simulated chest and arm portions. Combining the system disclosed by Eggert et al with the teaching of Takashina et at. provides a system that better represents the human body.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claims 8, 10, 13, 16, 19, and 27 Eggert et al discloses a simulator designed to represent a patient, such as a manikin, with a plurality of sensors and electronic signals to represent a plurality of physical diagnostic signals such as anyone of a plurality of body noises including heart and lung sounds (Col 4, lines 46-62). Eggert et al does not specifically disclose that a

tactile pulse simulator comprises any one of a tactile switch, collapsible tube apparatus or piezoelectric transducer (claims 8 and 16) of that the tactile simulator comprises a resilient cover . over a tactile switch (claims 10, 13 and 19). However, Takashina etal teaches that a simulated pulse may be derived from a collapsible tube apparatus built within a simulator comprising a manikin (Col 2, lines 22-35). Takashina also teaches that the tube apparatus is made of a soft rubber or synthetic resin so as to reproduce feeling in a finger that is similar to the human body diagnosis (Col 2, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator comprising a manikin with a tactile pulse simulator consisting of a collapsible tube apparatus with a resilient cover over a tactile switch. Combining the patient simulator disclosed by Eggert et al with the teaching of Takashina et al produces a training simulator that has the appearance of a human system and provides a realistic pulse tactile signal.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

Regarding claim 12, Eggert et al discloses a simulator, apparatus wherein pulse simulation signals are detected in a simulated arm in a first housing and audio is detected from the chest, a second housing (Col 6, lines 27-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in the wrisf of the simulator (claim 12). However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and the audio simulator located in the _chest portion. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator that most closely matches the audio and pulsation locations ona human body.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claim 14, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm ina first housing and audio is detected from the chest (Col 6, lines 26-52). Eggert et aI does not specifically disclose that the tactile sensor and the audio sensor are located in two separate housings. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) and that the audio sensor may be located in a second housing (Col 2, lines 52-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and the audio simulator located in the chest portion. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator that provides a more accurate teaching methodology for students.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claim 15, Eggert et a1 discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm and audio is detected from the chest (Col 6, lines 26.-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in the wrist of the simulator or that the tactile simulator comprises a resilient cover over a tactile switch. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) and that a tube apparatus is made of a soft rubber or synthetic resin so as to reproduce feeling in a finger that is similar to the human body diagnosis (Col 2, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and that the tactile simulator comprises a resilient cover over a tactile switch. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator in which diagnosis points are located in a fashion to emulate the human body for better training of medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claims 18, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm (Col 6, lines 26-52). Eggert et at does not specifically disclose that the tactile sensor for the pulse is located in either wrist of the simulator. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) including pulsation points in both left and right wrists. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in both a right and left simulated wrist in the body of the simulator. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator with the ability for multiple use by training professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claims 20 and 22, Eggert et al discloses a simulator apparatus for generating pulse and heart beat simulations comprising a simulated upper body portion with a chest and left and right arm portions, a playback device for generating electronic signals corresponding to pulse and heartbeat signals, a tactile pulse simulator and a heart beat signal within the chest housing of the simulator with the heart beat detectable by a stethoscope (Col 2 and Col 3). Eggert et al doe~ not specifically disclose a left and right pulse signal, or that the pulse signal is a pressure pulse signal. However, Takashina teaches that a pressure pulse signal may be generated through flexible tubing (Col 2, lines 23-53) and that pulsation signals are sent to detection locations on both the right and left wrist of a manikin simulator (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a training simulator apparatus for generating pulse and heart beat simulations comprising a simulated upper body portion, a playback device for generating electronic signals corresponding to pulse and heartbeat signals, a tactile pulse simulator and a heart beat signal within the chest housing of the simulator with the heart beat detectable by a stethoscope with detectable pulsation signals in a left and right wrist location. Combining the apparatus disclosed in Eggert et al. with the teaching of Takashina produces a training simulator that closely resembles the subjects for which the simulator is designed providing a realistic training environment for medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claim 21 and 26, Eggert et al discloses a simulator designed to represent a patient, such as a manikin, with a plurality of sensors and electronic signals to represent a plurality of physical diagnostic signals such as any one of pulse, heart beat, or lung sounds (Col 4, lines 25- 62). Eggert et al does not specifically disclose that the tactile, pulse simulator comprises any one of a tactile switch, collapsible tube apparatus or piezoelectric transducer.. However, Takashina et al teaches that a simulated pulse may be derived from a collapsible tube apparatus as a tactile pulse simulator built within a simulator comprising a manikin (Col 2, lines 22-35). Therefore it , would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator comprising a manikin with a tactile pulse simulator. Combining the patient simulator disclosed by Eggert et al with the teaching of Takashina et al produces a training simulator that has the appearance of a human system and provides a realistic pulse tactile signal.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claim 23, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm (Col. 6, lines 26-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in either wrist of the simulator. However , Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) including pulsation points in both left and right wrists. Therefore, if would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in both a right and left simulated wrist in the body of the simulator. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator with the ability for multiple use by raining professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claim 24, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm and audio is detected from the chest (Col 6, lines 26-52). Eggert et at does not specifically disclose that the tactile sens6rforthe pulse is located in the wrist of the simulator or that the tactile simulator comprises a resilient cover over a tactile switch. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) and that a tube apparatus is made of a soft rubber or synthetic resin so as to reproduce feeling in a finger that is similar to the human body diagnosis (Col 2,lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and that the tactile simulator comprises a resilient cover over a tactile switch. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator in which diagnosis points are located in a fashion to emulate the human body for better training of medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

> Regarding claim 25, Eggert et al discloses a simulator apparatus for generating pulse and heart beat simulations comprising a simulated upper body portion with a chest and left and right arm portions, a playback device for generating electronic signals corresponding to pulse and heartbeat signals, a tactile pulse simulator and a heart beat signal withing the chest housing of the simulator with the heart beat detectable by a stethoscope (Col 2 and Col 3). Eggert et al does not specifically disclose a left and right pulse signal, or that the pulse signal is a pressure pulse signal. However, Takashina et al teaches that a pressure pulse signal may be generated through flexible tubing (Col 2, lines 25-53) and that pulsation signals are sent to detection locations on both the right and left wrist of a manikin simulator (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art to

provide a simulator apparatus for generating pulse and heart beat simulations comprising simulated upper body portion with a chest and left and right arm portions, a playback device for generating electronic signals corresponding to pulse and heartbeat signals, a tactile pulse simulator and a heart beat signal within the chest housing of the simulator with the heart beat detectable by a stethoscope as disclosed by Eggert et al with detectable pulsation signals in a left and right wrist location as taught byt Takashina et al for the purposes of producing a training simulator that closely resembles the subjects for which the simulator is designed providing a realistic training environment for medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. **Again, Eggert et al. does not include a pulse simulation device and Applicant has removed Takashina et al.** Applicant, therefore, respectfully requests withdrawal of this rejection.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000

Date: **June 17, 2004**

Respectfully submitted,

Robert W. Strozier
Reg. No. 34,024